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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,692	01/05/2006	Marlene A. Jacobson	21254P	3011

210 7590 01/23/2008
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EXAMINER

HOWARD, ZACHARY C

ART UNIT	PAPER NUMBER
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1646

MAIL DATE	DELIVERY MODE
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01/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/563,692

Applicant(s)

JACOBSON ET AL.

Examiner

Zachary C. Howard

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-10,19,21,23-29 and 31-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-5,7-10,19,21,23-29 and 31-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 12/7/07 has been entered in full. Claims 1-5, 8, 21, 23-25, 27-29, 31-33 and 35-38 are amended. Claims 6, 11-18, 20, 22, 30 and 39 are canceled.

Claims 1-5, 7-10, 19, 21, 23-29 and 31-38 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 7-10, 19, 21, 23-29, 31-33 and 35-38, drawn to methods of screening using cells co-expressing a cell surface receptor protein and a neurotransmitter transport protein specific for a ligand of said cell surface receptor protein.

Group II, claim 34, drawn to "host cells transformed with a nucleic acid construct under conditions favoring expression of at least one metabotropic glutamate receptor protein on a surface of said cells and a non-human neurotransmitter protein specific for a ligand of said receptor protein."

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I and II appears to be that they all relate to a host cell of Group II. Specifically, Group I is related to methods of use of said host cells and Group II is related to the host cells *per se*.

However, Krapcho et al, U.S. Patent 6,534,287 (published 3/18/03 and filed on 10/24/00; cited as Reference #1 on the 1/8/07 IDS) teaches a host cell with all of the

limitations of this technical feature. Krapcho teaches, "a newly identified splice variant of human metabotropic glutamate receptor 5 (mGluR5). The novel human receptor may be expressed in host cells which may be used to screen for agonist, antagonist, and modulatory molecules that act on the novel human mGluR5" (col 1, lines 14-18). Krapcho further teaches in Example 4, "To prevent tonic activation of hmGluR5d by glutamate that may be released by these cells into the extracellular medium, hmGluR5d was transfected into a clonal HEK293 cell line expressing a glutamate/aspartate transporter (GLAST) from a mammalian expression vector with Zeocin resistance (Desai et al. (1995), Mol. Pharm. 48:648)" (col 28, lines 12-18). The GLAST taught by Desai is a murine glutamate transporter. Thus, Krapcho teaches a host cell transformed with a nucleic acid construct under conditions favoring expression of at least one metabotropic glutamate receptor protein on a surface of said cells (e.g., human mGluR5 glutamate receptor) and a non-human neurotransmitter protein specific for a ligand of said receptor protein (e.g., GLAST, a murine glutamate transporter). Therefore, the technical feature linking the inventions of group I and II does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Elections of Species

Two elections of species are required as follows.

(1) This application contains claims directed to the following patentably distinct species of "cell surface receptor protein": mGluR-1, mGluR-2, mGluR-3, mGluR-4, mGluR-5, mGluR-6, mGluR-7 and mGluR-8. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Currently, claims 1, 3-5, 7-10, 19, 21, 23, 24, 27-29 and 31-38 are generic; claim 2 recites each species as a Markush-type group, and claims 25 and 26 are each directed to a single species (mGluR5 or mGluR4, respectively).

(2) This application contains claims directed to the following patentably distinct species of measurable cellular response: (1) change in intracellular calcium concentration; (2) change in level of inositol phosphate; (3) change in cyclic AMP release; and (4) change in membrane potential.

Currently, claims 1, 2, 7, 24-28, 31, 32, 33 and 35-38 are generic; claims 3 and 23 are directed to species #1; claim 4 is directed to species #2; claims 5 and 29 are directed to species #3; and claims 8-10, 19 and 21 are directed to species #4.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of (1) cell surface receptor protein and (2) measurable cellular response for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

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prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646